

VALIDATION RESULTS FOR METHOD ACNE					
ANALYTE MATRIX DATE	Acetonitrile Exhale 7-Sep	MEAN	RELATIVE STD. DEV. (%)	RANGE	SEE (conc)
LLOQ	(Provide Statistical Criterion)	6.07 µg/mL	5.83	5.43 - 6.41	0.145
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) (SEE = S.D./SQRT (# of determinations))					
Representative		High QC 60.0µg/mL Med QC 30.0µg/mL Low QC 0.15.0µg/mL	5.72 8.40 4.82	50.0 - 58.7 21.8 - 30.0 13.0 - 15.2	
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quadratic, etc.) (Representative)	Linear (1/X weighting)				
Slope	2549				
Intercept	1556				
Other (R)	0.99943				
RECOVERY (as a %)					
High QC in (matrix)= 60.0µg/mL	90.1	5.72	83.3 - 97.8	1.38	
Med QC in (matrix)= 30.0µg/mL	89.2	8.41	72.7 - 100	2.00	
Low QC in (matrix)= 15.0µg/mL	93.8	4.81	86.7 - 101	1.21	
Results with different sample amounts (results of QC evaluations) intra-assay					
Representative					
LLOQ QC= 7.50µg/mL	6.07	5.83	5.43 - 6.41	0.145	
Low QC= 15.0µg/mL	14.1	5.04	13.1 - 15.1	0.290	
Med QC= 30.0µg/mL	27.0	8.19	23.6 - 30.1	0.902	
High QC= 60.0µg/mL	53.5	5.08	84.3 - 94.3	1.11	
Results with different sample amounts (results of QC evaluations) inter-assay					
Representative					
LLOQ QC= 7.50µg/mL	6.07	5.83	5.43 - 6.41	0.145	
Low QC= 15.0µg/mL	14.1	4.82	13.0 - 15.2	0.182	
Med QC= 30.0µg/mL	26.8	8.40	21.8 - 30.0	0.601	
High QC= 60.0µg/mL	54.0	5.72	50.0 - 58.7	0.826	
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)	60.0µg/mL	93.0			
b) Freeze/thaw (+/- % /3 cycles)	60.0µg/mL	103			
c) Injector (+/- %/24 hrs)	60.0µg/mL	97.2			

Exhale Summary  
10:08 PM 9/20/01

Analyst: \_\_\_\_\_  
Reviewed By: \_\_\_\_\_

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